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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,513	09/16/2003	Marc K. Hellerstein	416272003700	4651

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EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 08/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,513	HELLERSTEIN, MARC K.	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-29, drawn to a method for assessing metabolic fitness of aerobic demand of a living system, comprising administering an isotopically labeled molecule to the system, measuring, and calculating the rate of synthesis or degradation, classified in class 436, subclass 57 for example.

II. Claims 30-38, drawn to a method of identifying a drug agent capable of altering metabolic fitness or aerobic demand of a living system comprising, assessing metabolic fitness or aerobic demand, administering drug agent, and assessing metabolic fitness or aerobic demand, classified in class 435, subclass 4 for example.

III. Claims 39-47, drawn to a method of identifying a drug agent capable of altering metabolic fitness or aerobic of a living system comprising, assessing pre-existing metabolic fitness or aerobic demand of two living systems, comparing metabolic fitness or aerobic demand of treated to untreated system, classified in class 435, subclass 4 for example.

IV. Claims 48-51, drawn to a kit for assessing metabolic fitness of a living system, classified in class 424, subclass 1.11 for example.

V. Claim 52, drawn to a drug agent capable of altering metabolic fitness or aerobic demand of a living system, classified in class 424, subclass 9.2 for example.

VI. Claim 53, drawn to a drug agent capable of altering metabolic fitness or aerobic demand of one living system, when compared to a second living system, classified in class 424, subclass 9.2 for example.

VII. Claim 54, drawn to an isotopically perturbed mitochondrial DNA, classified in class 424, subclass 1.73 for example.

VIII. Claim 55, drawn to an isotopically perturbed cardiolipin, classified in class 424, subclass 1.11 for example.

IX. Claim 56, drawn to one or more isolated isotopically perturbed mitochondrian, classified in class 424, subclass 1.17 for example.

X. Claim 57, drawn to an isotope labeled precursor molecule, classified in class 424, subclass 1.37 for example.

XI. Claim 58, drawn to an isolated isotope labeled mitochondrial molecule made by administering an isotope labeled precursor molecule to a host organism for a time period sufficient for an isotope label to become incorporated into a mitochondrial molecule, classified in class 424, subclass 1.21 for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions employ different method steps, wherein each respective Group does not require the particulars of any other Group. One would therefore not have to practice the various methods at the same time to practice just one method alone, for example; Group I does not require the particulars of Groups II and III, i.e., the administration of a drug agent. Group II does not require the particulars of Groups III, i.e., the presence of a second living system or a mitochondrial molecule.

Inventions IV-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are physically and functionally unique and the particulars of one Group are not required for any other. For instance, Group VII refers to an isolated isotopically perturbed mitochondrial DNA, which is a physically and functionally distinct chemical entity from either isolated isotopically perturbed cardiolipin (Group VIII), one or more isolated isotopically perturbed mitochondrian (Group IX), or any unspecified isotope labeled precursor or mitochondrial molecule (Groups X and XI).

Inventions I-III with V-XI are related as process of identifying and product identified. The inventions can be shown to be distinct if either or both of the following can be shown: (1) that the method as claimed can be practiced with another materially different product or (2) the product as claimed can be identified by another and materially different method (MPEP § 806.05(h)). In the instant case, the agents of Groups V-XI could be identified by a materially different process than as set forth in Groups I-III. For example, the drug agent could be identified through the use of mass spectroscopy, gas chromatography or the use of a non-radioactive probe suc as a mitochondian specific fluorescently tagged precursor molecule.

Inventions I-III with IV are related as kit and method for use. The inventions are distinct in that: 1) the methods can be performed without the kit and 2) that isotopically labeled water is not required by Groups I-III.

The search for the above inventions would not be co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: 1) isotopically labeled precursor molecule, 2) living system, 3) mitochondrial molecule and 4) a drug agent.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

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PATRICIA LEITH
PRIMARY EXAMINER